FDA Sounds Alarm on Phony Tamiflu

he FDA is warning consumers that a phony version of an antiviral drug being sold on the Internet could spark a harmful reaction in some people.

Investigators found the drug was being sold as "generic Tamiflu," even though FDA has not approved a generic version of Tamiflu, which is used in treatment of the flu.

The unapproved medication contains cloxacillin, an ingredient in the same class as penicillin. FDA warned that the unlabeled product could result in a life-threatening reaction in persons who are allergic to penicillin.

FDA investigators bought the fake Tamiflu without a prescription on the Internet, but a prescription is required to buy Tamiflu in legitimate pharmacies. Later, two foil-backed blister packages with a total of 30 yellow and tan capsules arrived in an envelope postmarked India. The product label claimed to be 75 mg. capsules of oseltamivir phosphate, but testing proved otherwise.

Tests conducted by FDA showed the product did not contain oseltamivir, the active ingredient in Tamiflu. Instead, the fraudulent medication contained cloxacillin.

"Medicines purchased from websites operating outside the law put consumers at increased risk due to a higher potential that the products will be counterfeit, impure, contaminated, or have too little or too much of the active ingredient," says FDA Commissioner Margaret A. Hamburg, M.D.

Severely allergic persons could



experience difficulty breathing, tightness in the chest, swelling of the throat or tongue, hives, dizziness, loss of consciousness, and a rapid or weak pulse. So far, FDA is not aware of any reports of adverse reactions.

FDA investigators routinely monitor the Web for the sale of unapproved drugs in an effort to protect the public, but the rapidly growing number of sites trafficking in fraudulent medicines means consumers must remain alert.

Officials advised consumers to learn how to buy medications on the Internet safely. Legitimate Internet pharmacies are licensed by a state board of pharmacy and follow laws and regulations.

Legitimate Internet pharmacies will also display a seal from the National Association of Boards of Pharmacy—known as VIPPS seal or Verified Internet Pharmacy Practice Sites. VIPPS pharmacies are listed at www.nabp.net/programs/accreditation/vipps/find-a-vipps-online-pharmacy/.

To learn how to buy drugs online, go

to: www.fda.gov/Drugs/ResourcesForYou/ Consumers/BuyingUsingMedicineSafely/ Buying MedicinesOvertheInternet/ default.htm

FDA advises consumers who have drugs misrepresented as generic Tamiflu not to use them. Instead contact FDA's Office of Criminal Investigations by calling 800-551-3989 or by visiting www.fda.gov/OCI.

Health care professionals and consumers may report adverse events related to the use of these products to the FDA's MedWatch by phone: 1-800-FDA-1088: fax 1-800-FDA-0178; or mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

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